

# Leading on Biosimilars

## 2017 AAM Biosimilars Council Conference



### MONDAY, SEPTEMBER 11, 2017

3:00 p.m. – 5:00 p.m.      **Biosimilars Council Board of Directors Meeting**

### TUESDAY, SEPTEMBER 12, 2017 – CONFERENCE DAY 1

7:30 a.m. – 8:30 a.m.      **Networking Breakfast**

8:30 a.m. – 8:45 a.m.      **Welcome and Introduction**

**Christine Simmon**

Senior Vice President, Policy & Strategic Alliances, AAM  
Executive Director, Biosimilars Council

8:45 a.m. – 9:15 a.m.      **Biosimilars Council Chair Welcome**

**Bruce Leicher**

General Counsel, Senior Vice President and Secretary  
Momenta Pharmaceuticals, Inc.

9:15 a.m. – 10:00 a.m.

**FDA Keynote**

**Leah Christl, Ph.D.** (Invited)

Associate Director, Therapeutic Biologics and Biosimilars Team  
Food and Drug Administration

10:00 a.m. – 10:30 a.m.      **Networking Refreshment Break**

- 10:30 a.m. – 12:00 p.m. **Market Access, Market Promise**  
**Moderator: Elizabeth Jex**  
Attorney Advisor, Office of Policy Planning  
Federal Trade Commission
- Crystal Kuntz**  
VP Policy and Regulatory Affairs  
America's Health Insurance Plans
- Andrew Mulcahy**  
Policy Researcher; Associate Research Department Director  
RAND Corporation
- Rachel Sher**  
Deputy General Counsel  
AAM
- 12:00 p.m. – 1:15 p.m. **Luncheon**
- 1:15 p.m. – 2:15 p.m. **Delivering Biosimilars Access in Europe**  
**Adrian van den Hoven**  
Director General, Medicines for Europe
- 2:15 p.m. – 3:15 p.m. **The Promise of Biosimilars: How Patient Advocates are Educating on the Role of Biosimilars in Patient Care**  
**Moderator: Edward Li, Pharm.D., MPH, BCOP**  
Professor, Department of Pharmacy Practice  
University of New England College of Pharmacy
- Christy Gamble, J.D., DrPH, MPH**  
Director, Health Policy and Legislative Affairs  
Black Women's Health Imperative
- Michele McCourt**  
Senior Director, CancerCare Co-Payment Assistance Foundation  
CancerCare
- Claire Saxton**  
Senior Director, Education  
Cancer Support Community
- Laura Wingate**  
Senior Vice President, Education, Support & Advocacy  
Crohn's & Colitis Foundation
- 3:15 p.m. – 3:30 p.m. **Networking Refreshment Break**

- 3:30 p.m. – 4:15 p.m. **Channel Vision: How Payers Influence the Biosimilars Market**  
**Eric Percher**  
Wall Street Analyst
- 4:15 p.m. – 5:00 p.m. **USP Biologics Program Overview**  
**Fouad Atouf, Ph.D.**  
Vice President, Science - Global Biologics  
U.S. Pharmacopeial Convention
- 5:00 p.m. – 7:00 p.m. **Networking Reception**

## **WEDNESDAY, SEPTEMBER 13, 2017 - CONFERENCE DAY 2**

- 8:00 a.m. – 9:00 a.m. **Networking Breakfast**
- 9:00 a.m. – 9:45 a.m. **CMS Keynote**  
**Seema Verma** (Invited)  
Administrator, U.S. Centers for Medicare and Medicaid Services
- 9:45 a.m. – 10:45 a.m. **Biosimilars at the Bar: Legal Issues**  
**Chad A. Landmon, J.D.**  
Partner, Axinn, Veltrop & Harkrider LLP
- 10:45 a.m. – 11:15 a.m. **Networking Refreshment Break**
- 11:15 a.m. – 12:15 p.m. **Lessons Learned from the FDA Approval Process**  
Moderator: **David Gaugh, R.Ph.**  
Senior Vice President of Regulatory Sciences  
AAM
- Cindy Cao, Ph.D.**  
Head, U.S. Biopharmaceutical Regulatory Affairs  
Sandoz Biopharmaceutical
- Tracy Dianis**  
Director, Global Regulatory Affairs Biosimilars  
Pfizer Essential Health
- John Pakulski** (Invited)  
Head, Regulatory Science, Biologics  
Mylan, Inc.

12:15 p.m. – 1:30 p.m.

***Luncheon***

1:30 p.m. – 2:15 p.m.

**Interchangeability – What is Next?**

***Hillel Cohen***

Executive Director, Scientific Affairs  
Sandoz Biopharmaceuticals

2:15 p.m. – 3:30 p.m.

**Biosimilars Discussion with Industry Leaders**

**Moderator: *Edric Engert***

Managing Director  
Abraxeolus Consulting

***Bruce Leicher***

General Counsel, Senior Vice President and Secretary  
Momenta Pharmaceuticals, Inc.

***Patrick Lucy***

Chief Business Officer  
Pfenex Inc.

***Dan Motto***

Senior Vice President, Business Development, Portfolio  
Management & Business Intelligence, Teva Pharmaceuticals, USA

***Carlos Sattler***

Vice President and Head of Clinical Development  
and Medical Affairs, U.S.  
Sandoz Biopharmaceuticals

***Mike Woolcock***

Senior Vice President, Commercial Operations  
Apobiologix

3:30 p.m. – 3:45 p.m.

**Closing Remarks**

***Bruce Leicher***

General Counsel, Senior Vice President and Secretary  
Momenta Pharmaceuticals, Inc.

3:45 p.m.

***Conference Concludes***